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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/075,144

Applicant(s)

RAO ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-44 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 7, 10-12, 15, 18-20 and 23-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 9, 13, 14, 16, 22, 28-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

DETAILED ACTION

*Response to Arguments*

1. Applicant's arguments with respect to the claim rejections under Camrud et al. have been considered but are moot in view of the new ground(s) of rejection. Examiner has found a new prior art reference that better anticipates the claimed invention. A new rejection in view of Veatch has been made. Therefore, the allowable subject matter indicated in the prior office action has been withdrawn.
2. Applicant is unsure why claim 21 was examined. Applicant elected the species in Figure 3A, but the listing of claims readable on that species was incorrect. Segment 32 in Figure 3A is a substitute for the segment 32 in Figure 2, so the elected embodiment also includes end pieces (20 and 40) that are not illustrated in Figure 3A. Claim 21 reads on the elected species because it includes end pieces with a cross sectional area larger than that of the body. Claims 5, 7, and 18 did not read on the elected species, so they were not examined.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3,6,9,13,14,16, and 36-44 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,294,260 to Veatch.

Veatch discloses a device for treating a body canal that is formed by a plurality of interconnected loops (12). The loops can move relative to one another along all three axes

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X, Y, and Z. There two end pieces (18 and 20), and end piece (20) has a cross-sectional area that is larger than that of the loops. There are tubular segments (14) connected to the loops and the segments (14) have an uneven surface.

Claim 31 is a product by process claim. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. Since claim 31 only refers to the process by which the structure is made, it is not given patentable weight.

Claims 28 and 29 only refer to intended use. Veatch states in the abstract that the device is intended for insertion in the urethra and bladder, so it meets the requirements of claims 28 and 29.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 22 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veatch.

As explained above, Veatch includes many of the limitations of claims 22-35, except for forming one of the end pieces to have a substantially spherical shape. End piece 18 does have a rounded tip 19 and end piece 20 has circular loop shape. Altering these shapes to be substantially spherical is only matter of design choice.

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The end pieces of both applicant and Veatch perform the same function of retaining the location of the device in the body. Applicant admits that the shape of end piece is a simple matter of design choice and gives multiple embodiments of possible shapes of end pieces:

a. Paragraph 0038 of the specification states, *"The proximal end-piece 20 and the distal end-piece 40 may serve as retention devices to hold the proximal and distal ends of the device 10 at a specific anatomical location. For example, a specific anatomical location includes but is not limited to the renal pelvis, urinary bladder, or a blood vessel. Each end-piece 20, 40 is depicted as an embodiment having a substantially spherical shape in FIGS. 1 and 2, however, the shape of the end-pieces 20, 40 include other embodiments known to the skilled artisan and are not limited to those illustrated."*

b. Figure 6C of the disclosure illustrates a loop shaped end piece 20/40 that is an equivalent substitute for the spherical end piece in Figure 2. This loop shaped end piece in Figure 6C is similar to that of Veatch.

In view of this evidence, it would have been an obvious matter of design choice to substitute a substantially spherically shaped end piece for the loop shaped end piece of Veatch.

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Veatch in view of US Patent No. 5,209,239 to Watanabe et al. and further in view of US Patent No. 6,214,037 to Mitchell et al.

Veatch does not form the members of biodegradable material. Watanabe discloses a similar examination chain formed as interconnected loops (14). Watanabe teaches that it

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is known for examination chains to be left in the patient for a period of time after it has been delivered into the body canal (column 1, lines 50-55). Mitchell discloses another device adapted for insertion into the urethra, bladder, or other body canal. Mitchell teaches that a device delivered to a body canal can be formed of a biodegradable material so that it does not have to be manually removed (column 4, line 58 through column 5, line 10). For example, the chain of Veatch could be formed of urine soluble material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the chain of Veatch from a biodegradable material, as taught by Watanabe and Mitchell, so that the chain can be left in the body for examination and removed by biodegradation instead of manual force.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhhuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW  
01/27/05

*Julian W. Woo*

**JULIAN W. WOO  
PRIMARY EXAMINER**